

**The FDA Is Overextended and Underfunded --
It Would Be Foolhardy for Congress to
Add Tobacco Products to Its Lengthy
List of Important Responsibilities**

Congressman Synar's latest anti-tobacco bill, H.R. 2147, seeks to give regulatory authority over tobacco products to the Food and Drug Administration ("FDA"). The FDA is already charged with the enormous responsibility of ensuring that the drugs, medical devices, vaccines, blood products and radiological products we use are safe and effective and that the foods we eat and the cosmetics we use are safe and truthfully labeled. Adding tobacco products to FDA's mandate would, as illustrated below, impose a burden the Agency can ill-afford and threaten to further compromise -- what Congress already has recognized -- FDA's hampered ability to meet its existing statutory burdens.

- ***The FDA's Statutory Duties Are Already Extensive and Are Likely to Keep Expanding.*** Since 1980, Congress has passed over 50 laws that affect FDA's responsibilities. Many of these statutes have imposed *major* requirements for additional resources on FDA and required FDA to promulgate detailed implementing regulations. Twenty-six bills are currently pending before Congress that would further extend FDA's responsibilities for products currently within its jurisdiction. Even if all of these bills are not enacted, FDA's statutory duties for the products it currently regulates are unlikely to stop growing during the foreseeable future.
- ***The Industries Regulated by FDA Are Expanding Rapidly.*** During the past decade, the food, drug, medical device and cosmetic industries have all expanded rapidly. The number of products regulated by the FDA has grown significantly (*e.g.*, 82% more experimental product applications were filed in 1989 than in 1980). New technological advances in each of the industries FDA regulates means that this expansion is likely to accelerate in the future.
- ***External and, in Some Cases, Unpredictable and Crisis-Like Issues Constantly Bombard the FDA, Increasing Its Workload.*** The explosion in biotechnology products, efforts to address the AIDS epidemic and the greater health care needs of an aging population represent a few of the external pressures that impact on FDA. The Clinton health care reform proposal will also have a significant impact on FDA resources and responsibilities. Other externalities include product tampering incidents, product recalls and other health and safety emergencies. In recent years, for example, we witnessed Sudafed tampering, syringes in Pepsi, ALAR on apples and problems with silicone breast implants.

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- ***Congress has Voiced Repeated Concern Over FDA's Inadequate Resources.*** As recently as June 16, 1993, Chairman Dingell told the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, that: "The FDA's ability to regulate imported drugs, foods, cosmetics and medical devices is not sufficient to protect the public adequately."

Similarly, in a May 12, 1993 letter to Members of the House Committee on Energy and Commerce, Representative Dingell said that FDA's Center for Devices and Radiological Health (CDRH) is "unable to either protect adequately the public from unsafe devices or to approve useful and safe devices in a reasonable period of time."

- ***The FDA's Inadequate Resources Have Led to Chronic Delays in its Product Approval Processes.*** The backlog of pending medical device applications recently exceeded 1,100 and drug approval times averaged 29 months in 1991. The lag from synthesis of a promising new chemical compound to approval for sale as a medicine is currently 14 years. In addition, approximately 80 percent of drugs approved by the FDA between 1987 and 1989 were available, on average, 6 years earlier in other countries.
- ***Inadequate Resources Have Created Serious Delays in Rulemaking.*** According to a February 1992 GAO report, the average published FDA rule proposal was not promulgated in final form for nine years; three-fourths of all published rule proposals were not promulgated for more than five years, and others took as long as 20 to 30 years to be fully implemented. For example, the Agency has yet to complete the review of over-the-counter drugs begun some 30 years ago and regulations regarding the following three statutes have not been promulgated -- the Generic Drug Price Competition and Patent Term Restoration Act of 1984; the Vaccine Compensation Amendments of 1987; and the Generic Animal Drug and Patent Term Restoration Act of 1988.
- ***Due to Resource Constraints, FDA's Inspection and Enforcement Activities Are Diminished.*** The rate at which FDA inspects domestic products and manufacturing plants is unacceptably low (e.g., based on recent inspection rates, the Agency will visit each of the 90,000 establishments subject to inspection every six years instead of every two years, as required by statute for drug and device establishments). The rate at which the Agency inspects imported products and foreign plants is frightening (e.g., from 1985 to September 1989, only 31 of the 3,399 registered foreign canneries were inspected). This means that contaminated foods and unsafe drugs and devices frequently reach American consumers.

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- ***FDA's Facilities Are Outdated And In Disrepair.*** Many FDA facilities could not pass an FDA inspection. The lack of adequate facilities undermines the quality of science performed in FDA's labs, undercuts decision-making and the credibility of FDA's scientific judgments, and decreases the morale of FDA's overworked staff.
- ***Chronic Resource Constraints Create An Environment In Which Employee Corruption Is Possible.*** When FDA's resources are stretched to their limit, adequate supervision of employees becomes difficult. This makes the Agency ripe for employee misconduct like the kind that resulted in the "generic drug scandal" and, more recently, criminal wrongdoing by former FDA import inspectors.

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Despite some recent progress, the FDA is still stretched to the limit. Adding tobacco products to the Agency's already full plate is foolhardy, not only because of the immense added responsibility, but also because it would move the FDA to the center of the smoking debate, tying the Agency into regulatory knots and diverting it from ensuring the safety of the nation's food and drug supply. All of this would be done to ensure the "safety" of a product that the very advocates of FDA regulation have repeatedly proclaimed can never be made "safe" or "safer."

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